Remarks

Claim 6 is amended. Claims 6, 10-14, 44-53 and 55-56 are pending in this application. The amendments to claim 6 are supported at page 24, lines 24-28. No new matter was added by way of amendment.

The allowability of claim 53 is acknowledged.

The 35 U.S.C. § 103(a) Rejection

Claims 6, 10-14 and 44-52 and 55-56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilmore (U.S. Patent No. 5,248,697) in view of Good (U.S. Patent No. 6,666,811) in view of Pellico (U.S. Patent No. 5,817,695). This rejection is respectfully traversed.

While Applicants can agree with much of the Examiner's characterization of the Wilmore patent, Applicants strongly disagree with the Examiner's characterization of Wilmore as teaching the oral administration of glutamine to a cancer patient. At Col. 6, lines 29-34, it is disclosed:

> Depending upon the severity of the disease, the glutamine can be administered intravenously, or can be incorporated into the diet.

While this may appear to suggest that glutamine can be mixed into food items at "0.1 to 2.0 grams per kilogram of body weight per day," this teaching is clarified at Col. 6, line 62-Col. 7, line 2:

> Glutamine can be administered alone or as a dietary supplement. When used as a dietary supplement, the glutamine can be mixed with an existing enteral or parenteral diet prior to administration to the patient. For example, glutamine can be incorporated in a standard total parenteral nutrition (TPN) formulation. Alternatively, the glutamine can be administered separately, without mixing it with other components of the diet.

Thus, it is clear, from a more complete reading of the specification, that the term "diet" refers to total parenteral nutrition solutions, not to conventional items of food and drink.

The Pellico patent does nothing to remedy the deficiencies of the Willmore patent. To begin, with the Pellico patent also does not disclose or suggest a composition that is ingested orally. The broadest description of the Pellico invention is at Col. 6, lines 31-46:

> An important object of this invention is to provide a new and improved diet for cancer patients through the formulation of enteral nutritional product...
> Another object of this invention is to provide a new and improved diet for cancer patients through the formulation of an enteral nutrition product which is high in fat, low in carbohydrates.... [emphasis added].

As noted by the Examiner, Pellico goes on to disclose solid compositions that are complex mixtures of fats, amino acids, carbohydrates, vitamins and salts. Example 1 discloses a composition that contains about 20% of a combination of sucrose and corn starch as the carbohydrate source. However, as described at Col. 12, lines 61-66:

> The diet[s] described herein will be the only source of nutrients for the patient. The diet is a powder which is adapted to be mixed with water and consumed.

While it is not possible to calculate the final percentage of carbohydrates present in the finished aqueous diet, it would necessarily be much less than the 20 wt-% carbohydrate recited in Applicant's claim 1. In fact, it is a stated aim of Pellico to reduce the amount of total carbohydrate in the compositions to the lowest possible level:

> The diet is extremely low in carbohydrates to prevent the tumor from using its preferred energy supply [Col. 7, lines 46-52]
>
> * * *
>
> The carbohydrate level, however, has been reduced to a low level. There is zero percent sucrose and the cornstarch has been lowered from 197 g/kg of diet to 20 g/kg. [Example 2]

In contrast, s presently claimed, in solution, the amount of carbohydrate exceeds the amount of glutamine by at least 4-fold, and can comprise 20-40% of the administered aqueous composition.

The Good patent discloses that many tumor cells are radio-resistant, and require higher doses of radiation than can be tolerated by normal tissues. However, the solution to this problem proposed by Good is not to protect normal tissues from high radiation doses with a protective agent, but rather to permanently implant "one or several radioactive microspheres which deliver continuous low dose radiation at the proper rate to cause a sustained G-2 cell block." [Col. 54, lines 55-66]. This is an opposite approach to that taken by Applicants and cannot be fairly read

to suggest the use of glutamine as a "radioprotection agent" potentiated by large amounts of carbohydrate. Therefore, withdrawal of this rejection is appropriate and is earnestly requested.

Double Patenting Rejection

Claims 6, 10-14, 44-52 and 55-56 were provisionally rejected under a non-statutory double patenting rejection, specifically over claims 18-24 of copending Application No. 10/903,500 in view of Pellico (U.S. Patent No. 5,817,695) and further in view of Good (U.S. Patent No. 6,666,811). This rejection is respectfully traversed.

The claims of the '500 application are directed to a method of monitoring glutamine supplementation by means of a marker protein in the blood. The present claims are not obvious in view of the claims of the '500 application and would not result in an untoward extension of the patent term of any patent to issue out of the present application, as the art would not motivate omission of the recited monitoring step. However, upon indication of allowable subject matter in this application, a terminal disclaimer will be filed, if appropriate, to moot any obviousness-type double patenting.

Conclusion

Applicants respectfully submit that the claims have been placed in condition for allowance, and notification of the allowance of the claims is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date March 6, 2007

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies ~~that this~~ correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 6th day of March 2007.

PATRICIA A.HULTMAN

Name

Signature